- 99. Moreover, in directly harassing and contacting Ms. Sindi over email, telephone, and text message, in appearing at Ms. Sindi's home and at events where she is scheduled to appear, among other actions, Defendants intended to inflict emotional distress upon the Plaintiff.
- 100. Samia and Ann El-Moslimany knew or should have known that emotional distress was likely to result from their conduct.
- 101. The actions described above were and are extreme and outrageous conduct.
- 102. Ms. Sindi has suffered harm due to emotional distress in the form of constant anxiety over her safety, even in her own neighborhood, in which Samia and Ann El-Moslimany have actively incited fellow Muslims to violence against her, with some posting comments that she should be "stoned."
- 103. Ms. Sindi's emotional distress was so severe and of a nature that no reasonable person could be expected to endure it.

Count V Permanent Injunction

- 104. Ms. Sindi sets forth here all foregoing paragraphs as if fully stated herein.
- 105. Ms. Sindi has been irreparably harmed in her reputation and in the reputation of her business enterprises by the malicious campaign of defamation conducted by Samia El-Moslimany and Ann El-Moslimany.
- 106. Unaware of their patent falsehood and incited by them, recipients of the El-Moslimanys' statements have made threats of violence against Ms. Sindi, suggesting, by way of one example only, that she should be "stoned."

- This has caused Ms. Sindi to fear for her physical safety and caused her emotional trauma for which there is and can be no economic compensation.
- 108. Samia and Ann El-Moslimany have vowed to set forth their defamatory campaign at all cost and without end.
- 109. In order to halt this malicious campaign of libel, slander, and defamation, Ms. Sindi has no adequate remedy at law.
- Ms. Sindi therefore asks this court to enjoin Samia El-Moslimany and Ann El-Moslimany from any and all acts of slander, libel, and defamation against her.

PRAYER FOR RELIEF AND JURY DEMAND

WHEREFORE, Plaintiff Hayat Sindi respectfully requests that this COURT

- 1. Enter judgment on all counts in favor of Ms. Sindi and award her damages in an amount to be determined by jury;
- 2. Declare that Defendants Samia El-Moslimany and Ann El-Moslimany have engaged in a campaign of slander, libel, and defamation against Ms. Sindi;
- 3. Enter a permanent injunction ordering Defendants Samia El-Moslimany and Ann El-Moslimany to cease and desist from spreading defamatory and false statements against Ms. Sindi;
- 4. Enter a permanent injunction ordering Defendants Samia El-Moslimany and Ann El-Moslimany to cease and desist from appearing at conferences or public events that Ms. Sindi attends in order to distribute libelous leaflets or otherwise engage in slander and libel against Ms. Sindi;
- 5. Enter a permanent injunction ordering Defendants Samia El-Moslimany and Ann El-Moslimany to cease maintaining the blog "TrueHayatSindi.BlogSpot.com" or any blog with Ms. Sindi as its subject;
- 6. Enter a permanent injunction ordering Defendants Samia El-Moslimany and Ann El-Moslimany to cease and desist in publication of malicious and false statements about Ms. Sindi in response to articles written about her;
- 7. Declare that Defendants Samia El-Moslimany and Ann El-Moslimany have tortiously interfered with Ms. Sindi's contractual relations;

- 8. Declare that Defendants Samia El-Moslimany and Ann El-Moslimany have tortiously interfered with Ms. Sindi's prospective business relations;
- 9. Declare that Defendants Samia El-Moslimany and Ann El-Moslimany have invaded Ms. Sindi's privacy;
- 10. Declare that Defendants Samia El-Moslimany and Ann El-Moslimany have intentionally inflicted emotional distress upon Ms. Sindi;
- 11. Grant Plaintiff Ms. Sindi her reasonably attorney's fees and costs; and
- 12. Award such other relief as the Court deems just and proper.

JURY DEMAND

HAYAT SINDI CLAIMS A RIGHT TO A TRIAL BY JURY ON ALL ISSUES AND CLAIMS SO TRIABLE

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Asst./Clerk

Dated: January 25, 2012

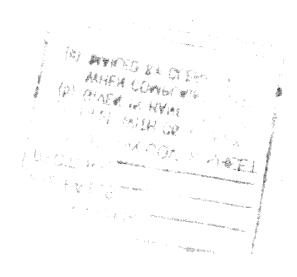
HAYAT SINDI,

By her attorneys,

David H. Rich (BBO# 634275) Michael Thad Allen (BBO# 679795)

TODD & WELD LLP 28 State Street, 31st Floor Boston, MA 02109 (617) 720-2626

drich@toddweld.com mallen@toddweld.com





UNIVERSITY OF LONDON

Hayat Sulaiman Sindi of King's College London

having completed the approved course of study and passed the examinations as an Internal Student in the Faculty of Science has this day been admitted by the Senate to the Degree of

BACHELOR OF SCIENCE

with Second Class Honours (Upper Division) in the following Field of Study: Pharmacology

Andow Rutheford

Vice-Chancellor

Principal, King's College London

1 August 1995



UNIVERSITY OF CAMBRIDGE

I hereby certify that

Hayat Sulaiman Sindi

of Newnham College

in the University of Cambridge was at a full Congregation holden in the Senate House on 24 March 2001 admitted to the Degree of

DOCTOR of PHILOSOPHY

Witness my hand this twenty-fourth day of March two thousand and one

Registrary of the University

Administrative Officer





OF OXFORD

DEPARTMENT FOR CONTINUING EDUCATION

This is to certify that

العلاق النَّفَاني السعودي في

بريطانيا وابرلندا عبدالله بن مدمد الله

Ms Hayat Sindi

attended a course organised by this Department on

An Introduction to Molecular Medicine

during the period

1-2 December 1999

CIP Thomas

Head of Department

Trit Wyatt

Director of Studies

CONTINUING PROFESSIONAL DEVELOPMENT CENTRE

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(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2009/0298191 A1 WHITESIDES et al.

(43) Pub. Date:

Dec. 3, 2009

(54) LATERAL FLOW AND FLOW-THROUGH BIOASSAY DEVICES BASED ON PATTERNED POROUS MEDIA, METHODS OF MAKING SAME, AND METHODS OF USING SAME

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(73) Assignee:

PRESIDENT AND FELLOWS OF HARVARD COLLEGE,

Cambridge, MA (US)

(21) Appl. No.:

12/425,121

(22) Filed:

Apr. 16, 2009

Related U.S. Application Data

- Continuation of application No. PCT/US2007/ 081848, filed on Oct. 18, 2007.
- (60) Provisional application No. 60/852,751, filed on Oct. 18, 2006.

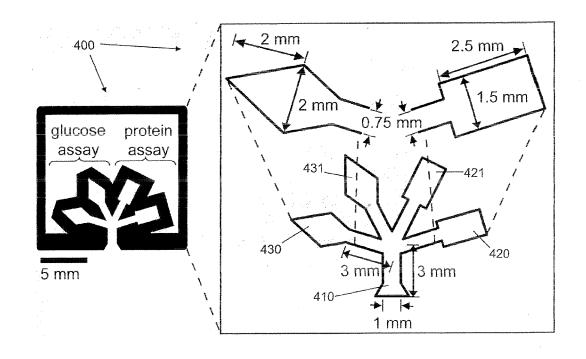
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	G03F 7/20	(2006.01)
	B29C 59/00	(2006.01)
	B05D 1/28	(2006.01)

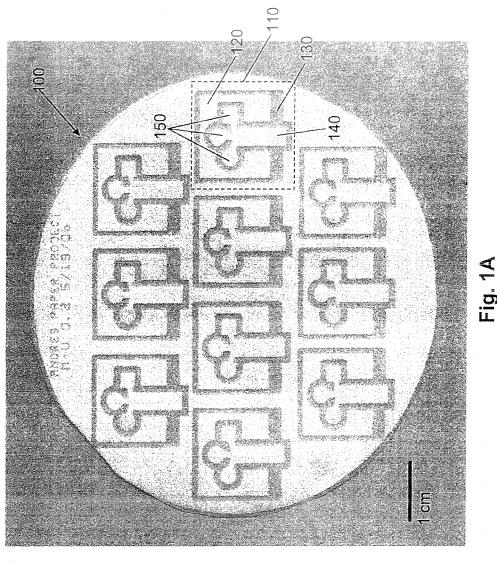
(52) U.S. Cl. 436/164; 422/56; 422/99; 430/325; 264/241

(57)ABSTRACT

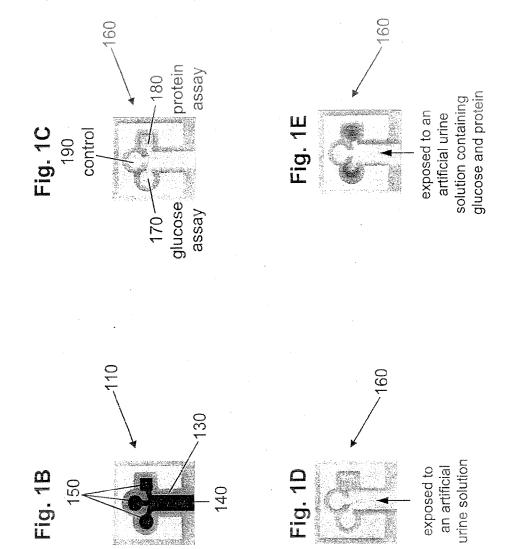
Embodiments of the invention provide lateral flow and flowthrough bioassay devices based on patterned porous media, methods of making same, and methods of using same. Under one aspect, an assay device includes a porous, hydrophilic medium; a fluid impervious barrier comprising polymerized photoresist, the barrier substantially permeating the thickness of the porous, hydrophilic medium and defining a boundary of an assay region within the porous, hydrophilic medium; and an assay reagent in the assay region.



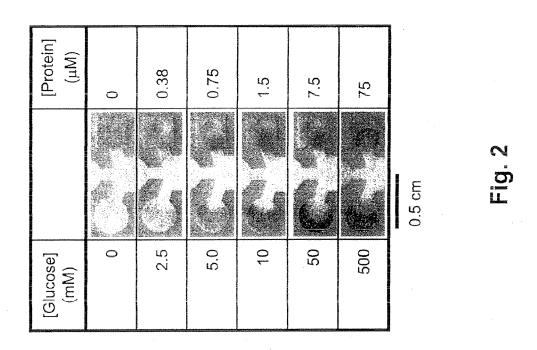
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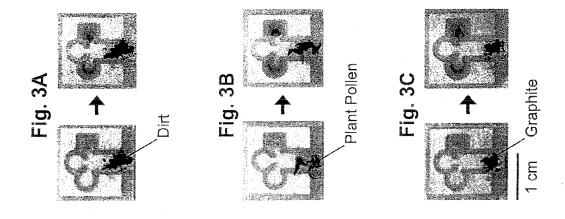
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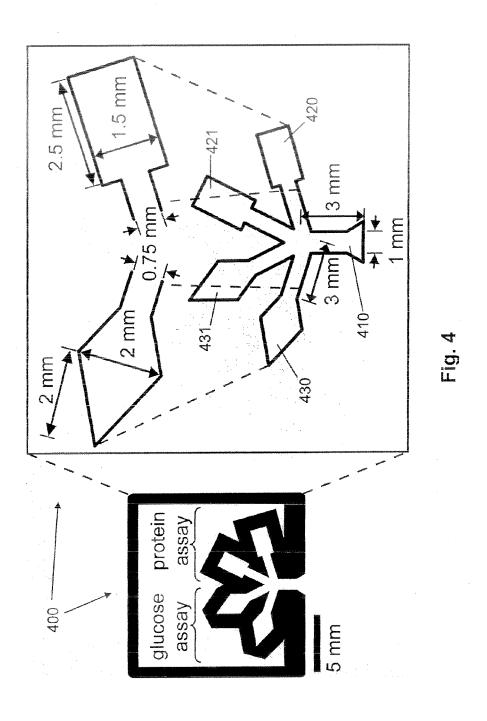
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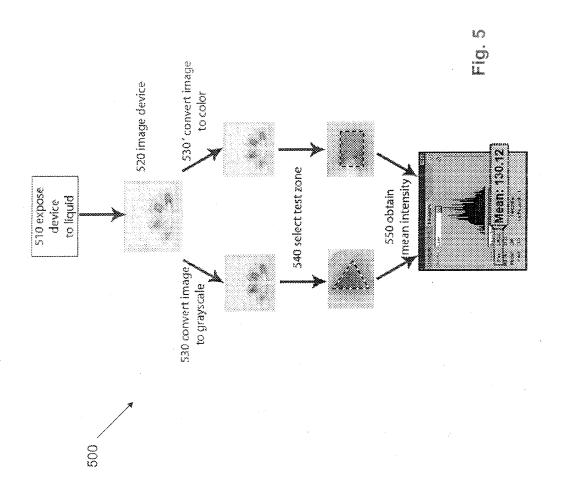
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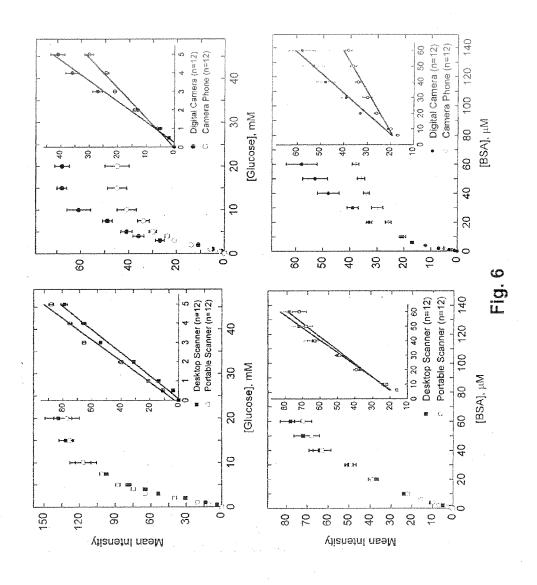
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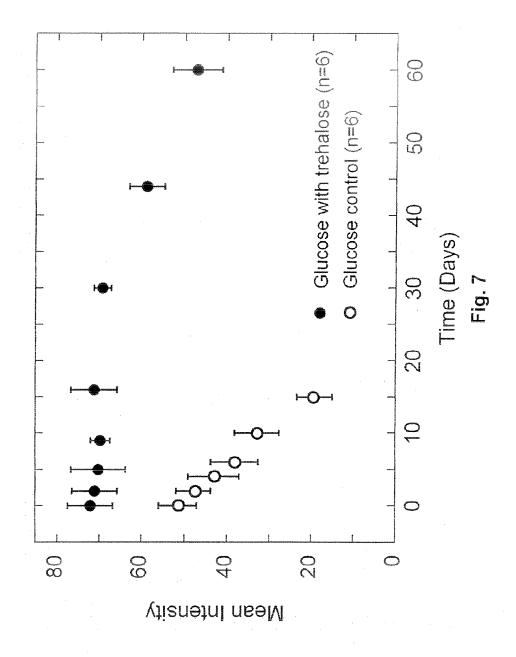
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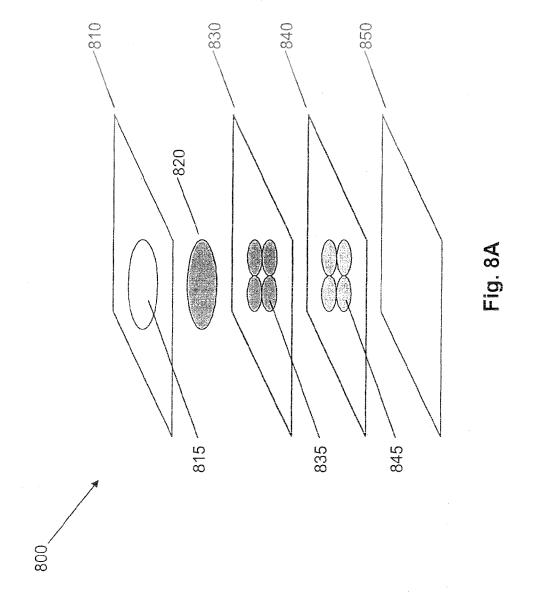
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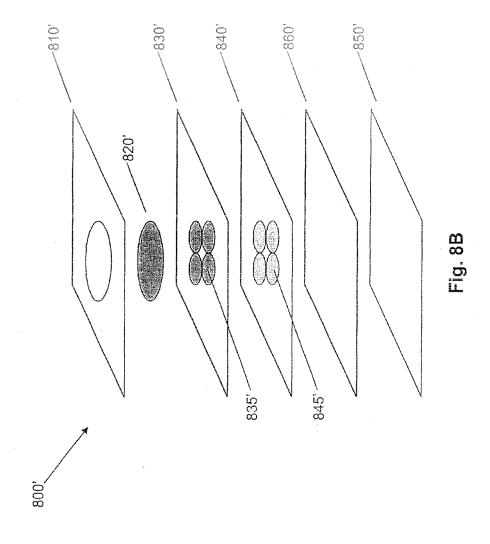
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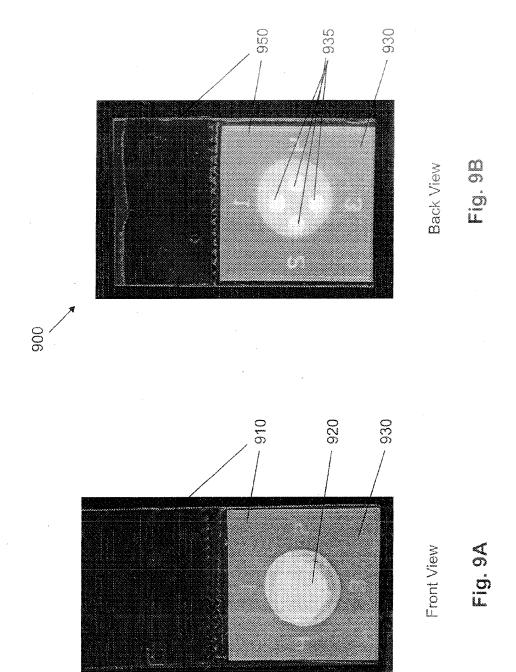
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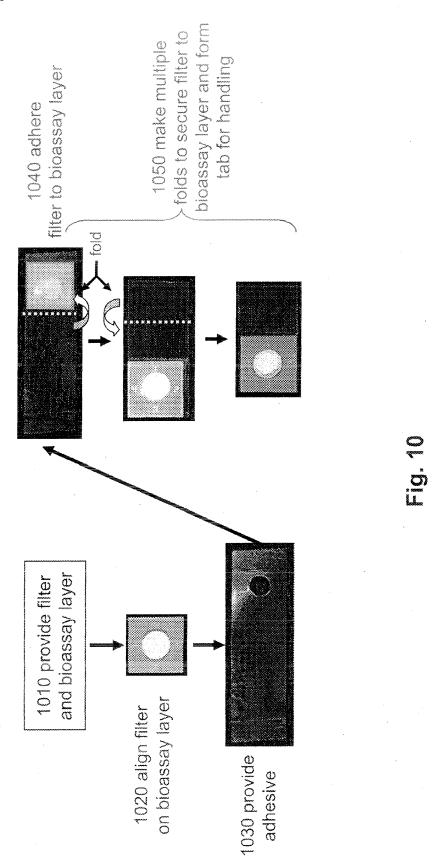


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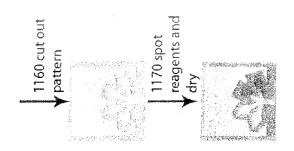


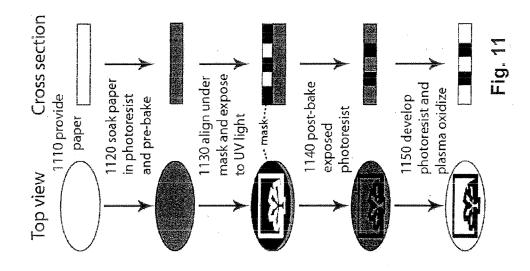
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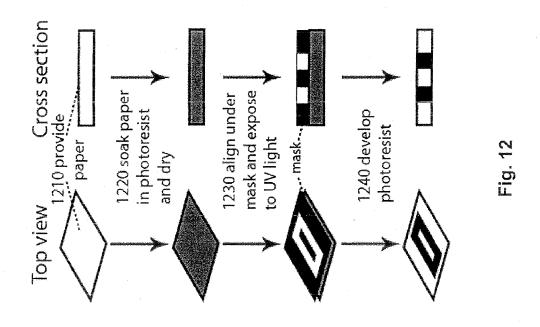


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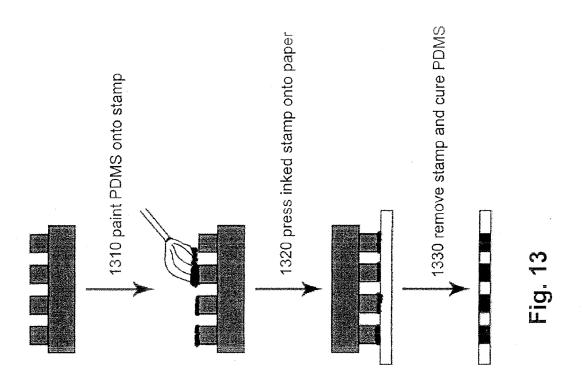




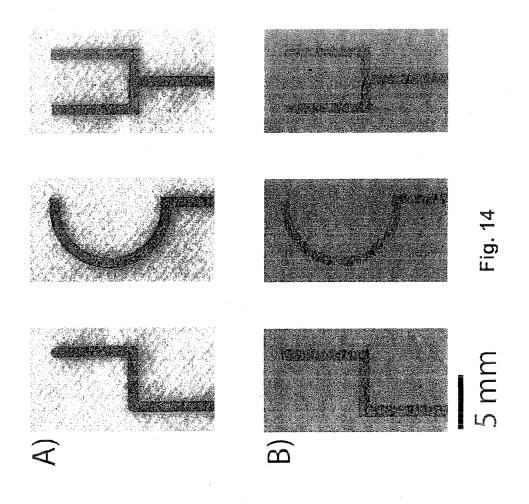
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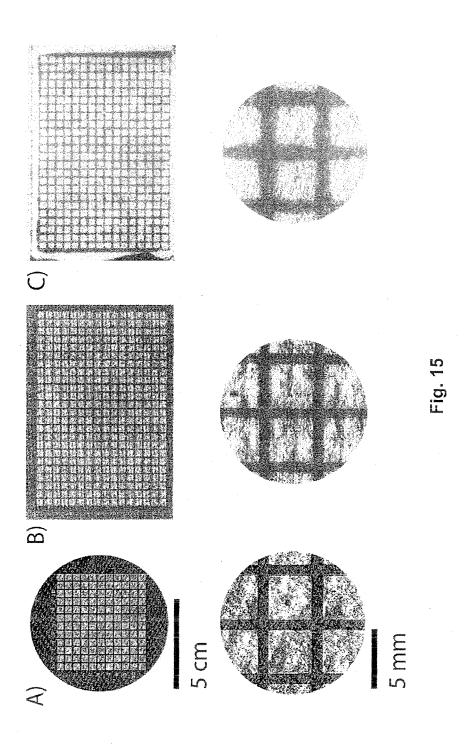
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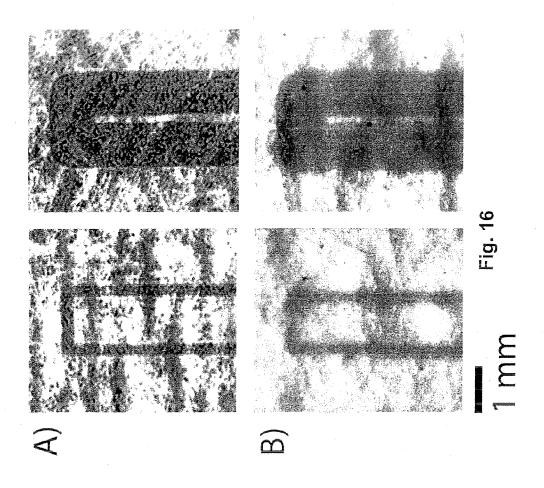
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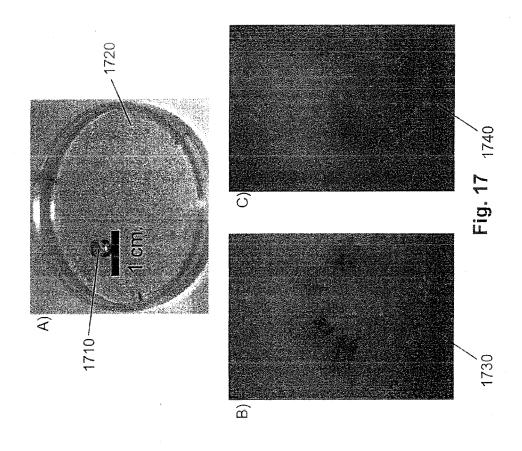
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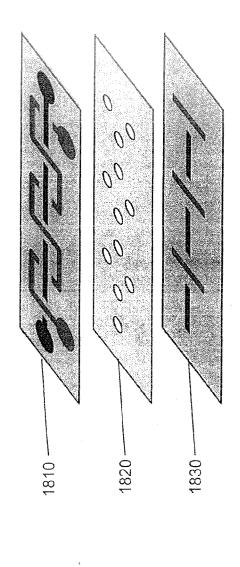
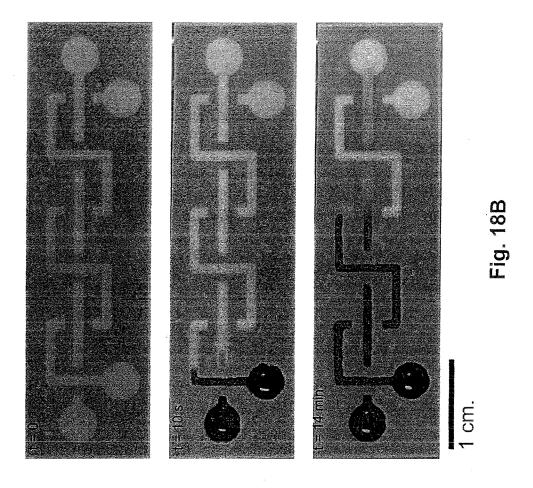


Fig. 18A

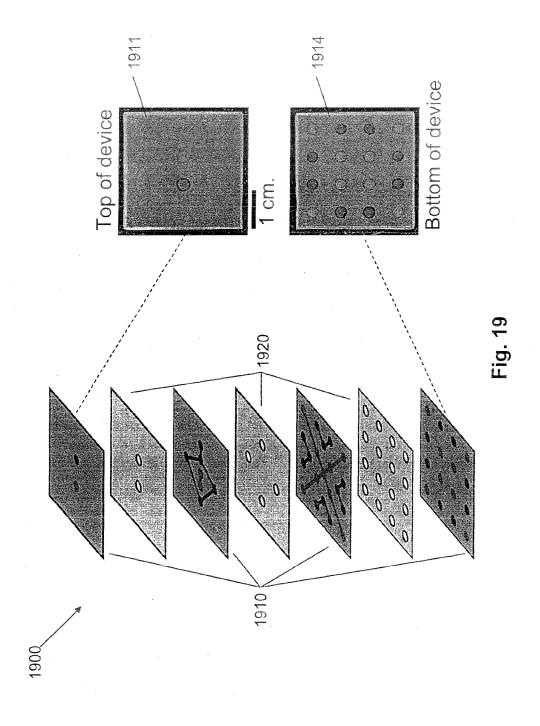
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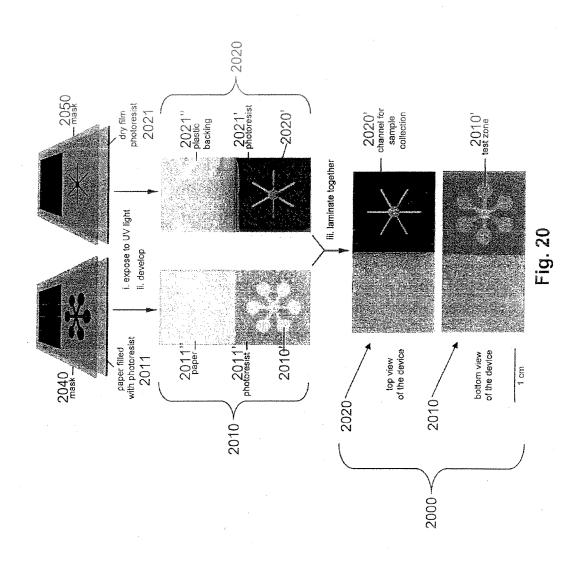


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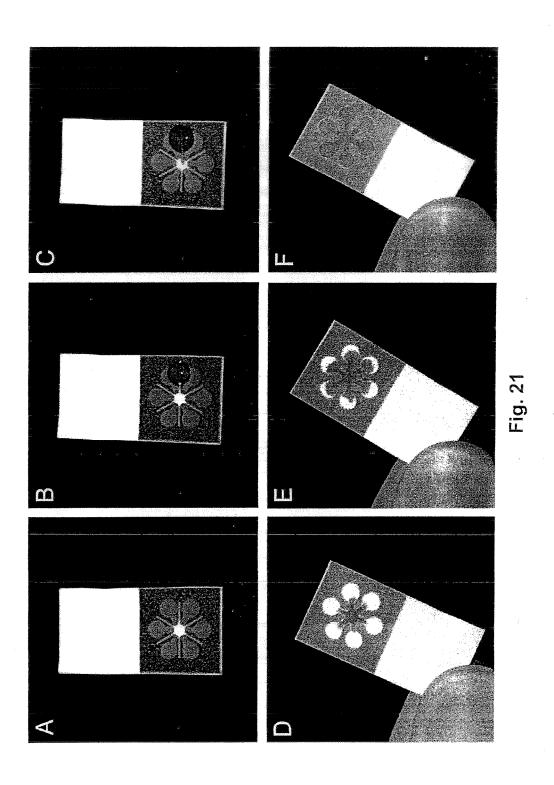
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LATERAL FLOW AND FLOW-THROUGH BIOASSAY DEVICES BASED ON PATTERNED POROUS MEDIA, METHODS OF MAKING SAME, AND METHODS OF USING SAME

RELATED APPLICATIONS

[0001] This application claims the benefit of priority under 35 U.S.C. §120 of Patent Cooperation Treaty Application No. US2007/081,848, filed Oct. 18, 2007, designating the United States and entitled "Lateral Flow and Flow-through Bioassay Based on Patterned Porous Media, Methods of Making Same, and Methods of Using Same," which claims the benefit of priority under 35 U.S.C. § 119(e) to U.S. Provisional Patent Application No. 60/852,751, filed Oct. 18, 2006, entitled "Patterned Paper as a Platform for Inexpensive, Low Volume, Portable Bioassays and Methods of Making Same," and U.S. Provisional Patent Application No. 60/914,252, filed Apr. 26, 2007, entitled "Patterned Paper as a Platform for Inexpensive, Low Volume, Portable Bioassays and Methods of Making Same," the entire contents of which are incorporated herein by reference.

STATEMENT OF GOVERNMENT SUPPORT

[0002] This research was supported by the National Institutes of Health (NIH) (GM065364), and the Materials Research Science and Engineering Centers (MRSEC) shared facilities supported by the National Science Foundation (NSF) under award no. DMR-0213805. This work was also supported by a predoctoral fellowship from NSF. The U.S. Government may have certain rights in this invention.

BACKGROUND OF THE INVENTION

[0003] This disclosure generally relates to bioassay devices based on porous media, methods of making same, and methods of using same.

[0004] The analysis of biological fluids is useful for monitoring the health of individuals and populations. However, these measurements can be difficult to implement in remote regions such as those found in developing countries, in emergency situations, or in home health-care settings. Conventional laboratory instruments provide quantitative measurements of biological samples, but they are typically unsuitable for remote locations since they are large, expensive, and typically require trained personnel and considerable volumes of biological samples.

[0005] Other types of bioassay platforms provide alternatives to conventional instruments, but they also have limitations in certain situations. For example, microfluidic devices can be useful in biological and chemical screening. Both glass and polymer-based microfluidic devices containing wells and/or channels have been developed. However, conventional microfluidic devices—even when designed to be simple—typically require pumps and external detectors for use.

[0006] While "dipsticks" are conceptually straightforward, they are generally too expensive for low-cost settings, and generally require a relatively large volume of sample in order to be able to make an accurate measurement, e.g., about 5 mL of sample. Such large volumes of samples are not obtained easily in many situations, particularly from premature infants and young children.

SUMMARY OF INVENTION

[0007] Under one aspect, a bioassay includes a porous hydrophilic medium capable of transporting fluids by capil-

lary action; and a fluid impervious barrier embedded in the porous hydrophilic medium, said barrier defining a channel terminating in one or more detection regions in the porous medium. In one or more embodiments, the porous hydrophilic medium is treated to provide a visible indication of an analyte present in a fluid.

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[0008] Under one aspect, an assay device includes a porous, hydrophilic medium; a fluid impervious barrier comprising polymerized photoresist, the barrier substantially permeating the thickness of the porous, hydrophilic medium and defining a boundary of an assay region within the porous, hydrophilic medium; and an assay reagent in the assay region.

[0009] One or more embodiments include one or more of the following features. The barrier further defines a boundary of a channel region within the porous, hydrophilic medium, the channel region fluidically connected to the assay region. The barrier further defines a boundary of a sample deposition region within the porous, hydrophilic medium, the channel providing a fluidic pathway within the porous, hydrophilic medium between the sample deposition region and the assay region. The barrier further defines boundaries of a plurality of assay regions. The barrier further defines boundaries of a plurality of channel regions within the porous, hydrophilic medium and further defines a boundary of a sample deposition region, each channel providing a fluidic pathway within the porous, hydrophilic medium between the sample deposition region and a corresponding assay region of the plurality of assay regions. Assay reagents in at least some of the assay regions. The barrier physically separates the assay regions of the plurality of assay regions from one another. The assay reagent is covalently bonded to the porous, hydrophilic medium in the assay region. The assay reagent is noncovalently bonded to the porous, hydrophilic medium in the assay region. The assay reagent is selected to provide a visible indication of the presence of analyte. The assay reagent is selected to react to the presence of at least one of glucose, protein, fat, vascular endothelial growth factor, insulin-like growth factor 1, antibodies, and cytokines. The photoresist comprises negative photoresist. The porous, hydrophilic medium comprises one of nitrocellulose acetate, cellulose acetate, cellulosic paper, filter paper, tissue paper, writing paper, paper towel, cloth, and porous polymer film. The porous, hydrophilic medium is flexible. The barrier has at least one dimension between about 5 cm and about 100 μm. The barrier has at least one dimension between about 300 µm and about 100 µm. The barrier has at least one dimension less than about 300 µm. The channel has at least one lateral dimension that is between about 750 μm and about 100 μm . The channel has at least one lateral dimension that is between about 250 µm and about 100 µm. The channel has at least one lateral dimension that is less than about 250 µm. An imaging device capable of obtaining a digital image of the assay region. A processor in communication with the imaging device and capable of obtaining information about an analyte in the assay region based on the digital image of the assay region. The processor is capable of obtaining the information about the analyte based on an intensity in the digital image of the assay region. A layer over the porous hydrophilic medium, the layer including at least one aperture. The aperture provides at least part of a fluidic pathway to the assay region.

[0010] Under another aspect, an assay device includes a porous, hydrophilic medium; a fluid impervious barrier substantially permeating the thickness of the porous, hydrophilic

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medium and having a width between about 1 mm and about 100 µm, the barrier completely defining a boundary of an assay region within the porous, hydrophilic medium; and an assay reagent in the assay region.

[0011] One or more embodiments include one or more of the following features. The assay reagent is selected to provide a visible indication of the presence of analyte. The assay reagent is selected to react to the presence of at least one of glucose, protein, fat, vascular endothelial growth factor, insulin-like growth factor 1, antibodies, and cytokines. The barrier comprises one of photoresist and curable polymer. The porous, hydrophilic medium comprises one of nitrocellulose acetate, cellulose acetate, cellulosic paper, filter paper, tissue paper, writing paper, paper towel, cloth, and porous polymer film. The barrier has at least one lateral dimension between about 300 µm and about 100 µm. The barrier has at least one lateral dimension less than about 300 µm. A plurality of fluid impervious barriers substantially permeating the thickness of the porous, hydrophilic medium, each barrier having a width between about 1 mm and about 100 µm, each barrier each completely defining a boundary of a corresponding assay region within the porous, hydrophilic medium; and an assay reagent in each assay region.

[0012] Under another aspect, an assay device includes a porous, hydrophilic medium; a fluid impervious barrier substantially permeating the thickness of the porous, hydrophilic medium and having a length and a width that varies by less than about 10% along the length of the barrier, the barrier defining a boundary of an assay region within the porous, hydrophilic medium, and an assay reagent in the assay region. [0013] One or more embodiments include one or more of the following features. The barrier further defines a boundary of a channel region within the porous, hydrophilic medium, the channel region fluidically connected to the assay region. The barrier further defines a boundary of a sample deposition region within the porous, hydrophilic medium, the channel providing a fluidic pathway within the porous, hydrophilic medium between the sample deposition region and the assay region. The assay reagent is selected to provide a visible indication of the presence of analyte. The assay reagent is selected to react to the presence of one of glucose, protein, fat, vascular endothelial growth factor, insulin-like growth factor 1, antibodies, and cytokines. The barrier comprises one of photoresist and curable polymer. The porous, hydrophilic medium comprises one of nitrocellulose acetate, cellulose acetate, cellulosic paper, filter paper, tissue paper, writing paper, paper towel, cloth, and porous polymer film. The barrier width is less than about 300 µm. The barrier width varies by less than about 5% along the length of the barrier. The channel region has at a width between about 750 µm and about 100 µm. The channel region has a length and a width that varies by less than about 10% along the length of the channel. The channel region has a length and a width that varies by less than about 5% along the length of the channel. [0014] Under another aspect, a method of making a device includes saturating a porous, hydrophilic medium with photoresist; exposing the saturated medium to a pre-determined pattern of light; removing the photoresist from a region of the medium based on the pre-determined pattern of light to define a barrier of residual photoresist that forms a boundary of the region, wherein the pre-determined pattern of light is selected so that the barrier defines an assay region in the region; and providing an assay reagent in the assay region.

[0015] One or more embodiments include one or more of the following features. The barrier is substantially fluid impervious. Selecting the pre-determined pattern of light so that the barrier completely encompasses the region. Selecting the pre-determined pattern of light so that the barrier borders a first portion of the region, and wherein an edge of the porous, hydrophilic medium borders a second portion of the region. Providing the reagent comprises covalently binding the reagent to the assay region. Providing the reagent comprises noncovalently binding the reagent to the assay region. Selecting wherein the pre-determined pattern of light so that the assay region has a shape based on transport characteristics of the reagent in the presence of a liquid. The assay reagent is selected to provide a visible indication of the presence of analyte. The assay reagent is selected to react to the presence of one of glucose, protein, fat, vascular endothelial growth factor, insulin-like growth factor 1, antibodies, and cytokines. Selecting the pre-determined pattern of light so that the barrier defines a channel region in the region. The channel region has at least one lateral dimension that is between about 750 μm and about 100 μm. Selecting the pre-determined pattern of light is selected so that the barrier defines a sample deposition region in the region. Saturating the porous, hydrophilic medium with photoresist comprises applying a solution of the photoresist in a solvent to the medium and substantially evaporating the solvent. Exposing the saturated medium to a pre-determined pattern of light comprises irradiating the region with the light and substantially not irradiating the barrier with the light. Exposing the saturated medium to a pre-determined pattern of light comprises irradiating the barrier with the light and substantially not irradiating the region with the light. Removing the photoresist comprises removing the photoresist from a plurality of regions of the medium based on the pre-determined pattern of light to define a plurality of barriers of residual photoresist that form boundaries of corresponding regions. Saturating a second porous, hydrophilic medium with photoresist; exposing the saturated second medium to a pre-determined pattern of light; removing the photoresist from a region of the second medium based on the pre-determined pattern of light to define a barrier of residual photoresist that forms a boundary of the region; substantially aligning the barrier of the second medium with the barrier of the first mentioned medium; and bonding the first medium to the second medium. Applying a reagent in the region of the first medium, the reagent selected to react to a target analyte. Providing one of a labeled antibody and a labeled protein in the region of the second medium, the one of the labeled antibody and the labeled protein selected to provide a color indication of a reaction between the reagent and the target analyte. Providing a layer over the porous, hydrophilic medium, the layer including at least one aperture that is aligned based on a position of the barrier. Selecting the predetermined pattern of light so that the barrier has at least one dimension that is between about 5 cm and about 100 µm. Selecting the pre-determined pattern of light so that the barrier has at least one dimension that is less than about 250 μm . The porous, hydrophilic medium comprises one of nitrocellulose acetate, cellulose acetate, cellulosic paper, filter paper, tissue paper, writing paper, paper towel, cloth, and porous polymer film. Removing the photoresist from a plurality of regions of the medium based on the pre-determined pattern of light to define a plurality of barriers of residual photoresist that form boundaries of a corresponding plurality of regions, wherein the pre-determined pattern of light is selected so that

the plurality of barriers define a corresponding plurality of assay regions in the regions; and providing an assay reagent in at least some of the assay regions.

[0016] Under another aspect, a method of making a device includes coating a stamp of pre-determined pattern with a curable polymer; pressing the coated stamp onto a porous, hydrophilic medium, the medium having a thickness and the curable polymer substantially permeating the medium through its thickness in accordance with the pre-determined pattern; curing the curable polymer so as to form a fluid impervious barrier embedded in the medium, the fluid impervious barrier defining an assay region in the medium; and providing a reagent in the assay region.

[0017] One or more embodiments include one or more of the following features. The curable polymer comprises poly (dimethyl-siloxane) (PDMS). Selecting the pre-determined pattern so that the barrier completely encompasses the region. [0018] Under another aspect, a method of performing an assay to determine the presence of an analyte in a liquid sample includes depositing the liquid sample on an assay device, the assay device comprising a porous, hydrophilic medium, a fluid impervious barrier comprising polymerized photoresist, the barrier substantially permeating the thickness of the porous, hydrophilic medium and defining a boundary of an assay region within the porous, hydrophilic medium, and an assay reagent in the assay region, the assay reagent selected to provide a visible response to the presence of the analyte; obtaining an image of the assay region; and determining the presence of the analyte in the liquid based on the image of the assay region.

[0019] One or more embodiments include one or more of the following features. Determining the presence of the analyte in the liquid comprises obtaining an average intensity of at least a portion of the image of the assay region, and determining the presence of the analyte in the liquid based on the average intensity. Obtaining the image of the assay region comprises imaging the assay region with one of a camera phone, a digital camera, and a scanner. Determining the presence of the analyte based on the image of the assay region comprises transmitting the image to a remote lab, and obtaining information from the remote lab regarding the presence of the analyte in the liquid. Obtaining the image of the assay region comprises imaging the assay region with a camera phone, and wherein determining the presence of the analyte based on the image of the assay region comprises transmitting the image to a remote lab via the camera phone.

BRIEF DESCRIPTION OF DRAWINGS

[0020] In the Drawing:

[0021] FIGS. 1A-1E are images of lateral flow bioassay devices, according to some embodiments.

[0022] FIG. 2 shows images of lateral flow bioassay devices exposed to solutions containing varying concentrations of analytes, according to some embodiments.

[0023] FIGS. 3A-3C depict lateral flow bioassay devices contaminated with dirt, plant pollen, and graphite powder, taken before and after exposure to solutions containing analytes, according to some embodiments.

[0024] FIG. 4 schematically illustrates a plan view of a lateral flow bioassay device for use in measuring the presence of glucose and protein in biological liquids, according to some embodiments.

[0025] FIG. 5 illustrates steps for using a lateral flow bioassay device to quantitatively determining the presence of analytes, e.g., glucose and protein in a biological liquid, according to some embodiments.

[0026] FIG. 6 illustrates the results of a quantitative determination of the presence of glucose and protein in biological liquids having varying concentrations of glucose and protein using a lateral flow bioassay device, according to some embodiments.

[0027] FIG. 7 illustrates the long-term stability of the flow device in the quantitative determination of the presence of glucose and protein in a biological liquid, with and without trehalose, according to some embodiments.

[0028] FIGS. 8A and 8B are perspective views of flow-through bioassay devices, according to some embodiments.

[0029] FIGS. 9A and 9B are front and back views, respectively, of an exemplary flow-through bioassay device, according to some embodiments.

[0030] FIG. 10 illustrates an exemplary method for assembling a flow-through bioassay device, according to some embodiments.

[0031] FIG. 11 illustrates an exemplary procedure for providing hydrophobic barriers in porous, hydrophilic media using photolithography in the cleanroom, according to some embodiments

[0032] FIG. 12 illustrates an exemplary procedure for providing hydrophobic barriers in porous, hydrophilic media using photolithography in the laboratory, according to some embodiments.

[0033] FIG. 13 illustrates an exemplary procedure for providing hydrophobic barriers in porous, hydrophilic media using microcontact printing, according to some embodiments.

[0034] FIGS. 14A-14B are images of hydrophobic barriers obtained using various methods of patterning, according to some embodiments.

[0035] FIGS. 15A-15C are images of grids of approximately 3.6×3.6 mm squares bounded by patterned hydrophobic barriers into paper formed using various methods of patterning, according to some embodiments.

[0036] FIGS. 16A-16B are images of widths of relatively narrow barriers that provide functional devices and are formed using various methods of patterning, according to some embodiments.

[0037] FIG. 17A is an image of an exemplary lens for use with camera phones, according to some embodiments.

[0038] FIGS. 17B-17C are images of a bioassay device taken, respectively, with and without the lens of FIG. 17A, according to some embodiments.

[0039] FIG. 18A illustrates a perspective view of a threedimensional bioassay device, according to some embodiments.

[0040] FIG. 18B shows images of an exemplary three-dimensional bioassay device at different times during exposure to colored liquids, according to some embodiments.

[0041] FIG. 19 illustrates a perspective view of a three-dimensional bioassay device, according to some embodiments

[0042] FIG. 20 illustrates plan and perspective views of layers in a lateral bioassay device, according to some embodiments.